

### **REMARKS**

Prior to the present amendment, claims 21-25 were pending. Claims 1-20 were canceled by a preliminary amendment filed July 19, 2005. By the present amendment, applicants have canceled claims 21-25 and added new claims 26-33. No new matter has been added. Accordingly, claims 26-33 are under examination.

### **Information Disclosure Statement**

On page 2 of the office action, the examiner states that the information disclosure statement filed on September 21, 2005 did not include a legible copy of each cited foreign patent document or each non-patent literature publication listed.

In response, applicants submit herewith a supplemental information disclosure statement. A copy of each of the cited references is enclosed.

### **Rejection under 35 U.S.C. § 112, Second Paragraph**

On pages 2-4 of the office action, the examiner rejects claims 21-25 as being indefinite for various reasons. Specifically, the examiner states in item 3 that claims 21-25 are indefinite because they do not set forth any steps in the method claims. In response, applicants have canceled claims 21-25. New claims 26-33 set forth steps in the method claims. Accordingly, applicants request reconsideration and withdrawal of the rejection.

In item 4, the examiner rejects claim 21 for being allegedly unclear about whether applicants intend to claim a method of manufacturing a medicament, a method of using a medicament, or a composition. In response, applicants have canceled claim 21. New claims 26-33 clearly recite a method of treatment. Accordingly, applicants request reconsideration and withdrawal of the rejection.

In item 5, the examiner rejects claim 21 as being indefinite for reciting the term “occlusive peripheral vascular disease, hemorrhoid disease.” The examiner states that it is unclear whether applicants intend to claim both diseases in conjunction, in the alternative, or some other option. In response, applicants have canceled claim 21. New claims 26-33 recite “A method for treating hemorrhoid disease.” Accordingly, applicants request reconsideration and withdrawal of the rejection.

In items 6-7, the examiner rejects claims 22-25 as being indefinite for depending upon a cancelled claim. In response, applicants have canceled claims 22-25. New claims 27-33 clearly depend upon presently pending claims. Accordingly, applicants request reconsideration and withdrawal of the rejection.

In item 8, the examiner rejects claim 25 as being indefinite for reciting the term “UI/g,” which the examiner states is not defined by the claim. In response, applicants have canceled claim 25. New claim 28 recites “IU per gram of the pharmaceutical composition.”

Support for this amendment can be found, for example, on page 5, third full paragraph, and on page 7, Example 1, of the specification as filed. The specification discloses the term “UI”, which stands for Unité Internationale, which is the established usage in most of the world excluding North America, where the alternative unit of “IU” (International Unit) are used. The units are interchangeable. As one skilled in the art readily understands, the International Unit can refer to activity of an enzyme. Accordingly, applicants request reconsideration and withdrawal of the rejection.

#### **Rejection under 35 U.S.C. § 101**

On page 5 of the office action, the examiner rejects claims 21-25 because the claims recite a use without setting forth any steps involved in the process. In response, applicants have

canceled claims 21-25. New claims 26-33 set forth steps in the method claims. Accordingly, applicants request reconsideration and withdrawal of the rejection.

**Rejection under 35 U.S.C. § 102 over Gelfand**

On page 5 of the office action, the examiner rejects claims 21-23 as being anticipated under 35 U.S.C. § 102(b) by the Gelfand reference (US 5,837,688). According to the examiner, Gelfand teaches a composition having peptides and proteins with thrombolytic action (e.g., streptokinase) for treatment of vascular disease. The examiner also states that Gelfand discloses rectal administration of the composition.

Applicants respectfully disagree. Applicants have canceled claims 21-23 and have added new claims 26-33, which are distinguishable from Gelfand. The claims now require a method for treating hemorrhoid disease in a human in need thereof. Gelfand is devoid of any disclosure or suggestion of a method for treating hemorrhoid disease. Accordingly, the claimed invention is not anticipated by Gelfand. Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection under 35 U.S.C. § 102 over Baldwin**

On pages 6-7 of the office action, the examiner rejects claims 21-25 as being anticipated under 35 U.S.C. § 102(b) by Baldwin, et al. (US 5,098,707). According to the examiner, Baldwin teaches compositions having proteins with thrombolytic action (e.g., streptokinase) for treatment of vascular disease. The examiner also states that Baldwin discloses rectal administration of the composition. Lastly, the examiner cites Baldwin for disclosing a composition that may contain recombinant streptokinase and that there may be 1.5 million units of streptokinase in the composition.

Applicants respectfully disagree. Applicants have canceled claims 21-23 and have added new claims 26-33, which are distinguishable from Baldwin. The claims now require a method

for treating hemorrhoid disease in a human in need thereof. Baldwin is devoid of any disclosure or suggestion of a method for treating hemorrhoid disease. Accordingly, the claimed invention is not anticipated by Baldwin. Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection under 35 U.S.C. § 103 over Gelfand and Baldwin**

On pages 7-10 of the office action, the examiner rejects claims 21-25 as being obvious under 35 U.S.C. § 103(a) over Gelfand and Baldwin. According to the examiner, Gelfand teaches a composition having peptides and proteins with thrombolytic action (e.g., streptokinase) for treatment of vascular disease. The examiner also states that Gelfand discloses rectal administration of the composition. The examiner acknowledges, however, that Gelfand does not specifically teach use of a recombinant streptokinase or use of the claimed amount of enzyme in the composition.

To compensate for the deficiencies of Gelfand, the examiner relies on the teachings of Baldwin as described above. According to the examiner, it was known that recombinant streptokinase could be used in compositions for rectal administration in amounts similar to the claimed amounts, as taught by Baldwin. The examiner further states that one skilled in the art would have had a reasonable expectation of success in combining the teachings of Gelfand and Baldwin because both references teach a composition having streptokinase with multiple carriers for rectal administration.

Applicants respectfully disagree. Applicants have canceled claims 21-23 and have added new claims 26-33, which are distinguishable from Gelfand and Baldwin. The claims now require a method for treating hemorrhoid disease in a human in need thereof. Gelfand and Baldwin, individually and in combination, are devoid of any disclosure or suggestion of a method for treating hemorrhoid disease. One of ordinary skill in the art would not have any reasonable expectation of success in combining these references to arrive at a method for treating

hemorrhoid disease. In example 5 of the application, applicants have disclosed successful results in treating hemorrhoid disease in humans. A significant number of patients experienced an improvement in healing and a reduction in swelling over a control group that was treated with typical, prior art medical treatments. Accordingly, the claimed invention is not obvious over Gelfand and Baldwin. Applicants respectfully request reconsideration and withdrawal of the rejection.

### **Conclusion**

In view of the foregoing amendments and remarks, entry of the amendments and favorable consideration of the claims are respectfully requested. If the examiner has any questions or concerns regarding this amendment, he or she is invited to contact the undersigned at the telephone number listed below. If any fees are due or any over overpayment made in connection with this paper, please charge or credit our Deposit Account No.: 08-2461.

Respectfully submitted,

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